Patent
Attorney Docket: 491,920-029
(prev 263/103)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

WALTER J. LEDERGERBER

Serial No.: 09/813,091

Filed: March 19, 2001

For: DUAL-SIDED, TEXTURIZED BIOCOMPATIBLE STRUCTURE

Group Art Unit: 3738

Examiner: David J. Isabella

REPLY UNDER 37 CFR § 1.116
EXPEDITED PROCEDURE
TECHNOLOGY CENTER 2800

DECLARATION OF DR. WALTER J. LEDERGERBER, M.D. UNDER 37 C.F.R. § 1.132

Mail Stop **AF**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Walter J. Ledergerber, M.D., do declare and state as follows:

1. I am a physician licensed to practice in the State of California. I have practiced in the field of plastic surgery since approximately 1982.

2. I received my Doctorate in Medicine (M.D.) from the University of California, Irvine in 1977. My residencies and training were in the fields of general surgery, plastic surgery and ear, nose and throat (ENT).

CERTIFICATE OF FACSIMILE
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to (703) 305-3580 on the date shown below addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Aug 25, 2003
Date of Deposit

Denise N. Doss

IR1:1046781.1

3. At the time of my inventions, which are the subject of this application, approximately December, 1987, I was personally acquainted with the state of the art in breast implants. I personally worked with the then available implants and observed firsthand the problems and deficiencies with them.

4. By way of example, the silicone elastomer implants suffered from the formation of scar tissue. Often the silicone elastomer would pull off from the scar tissue.

5. Attempts at making textured implants were unsuccessful. By way of example, a texturized implant made and sold by Dow Corning contained numerous individual projections from its surface, the surface being integrally connected to the implant.

6. My currently presented claims are to a sheet like structure of ePTFE. The ePTFE material is not interchangeable with or equivalent to silicone elastomer for sheet like applications. A silicone elastomer sheet could not by itself be sewn. Sewing (suturing or stapling) of my claimed sheet would be an essential requirement for the surgical use of the structure, such as for abdominal hernia repair.

7. I have reviewed the Netto (USP 4,573,999) and Mikulich et al. (USP 4,651,721) references, and the Office Action mailed July 11, 2003. I concur with the Examiner's reading of Netto as not disclosing the use of ePTFE. In contrast, Netto discloses the use of silicon rubber.

8. Mikulich et al. does not teach or suggest the interchangeability of ePTFE with silicone elastomer. Considering Mikulich et al. in detail, it teaches the use of ePTFE, but uses it for its anisotropic properties, namely the modulus of expansion differing in the longitudinal versus perpendicular direction.